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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KOSSON, ROSANNE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/615,515	GUTTERIDGE ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,11,19,20 and 24-65* is/are pending in the application.

4a) Of the above claim(s) *24-36, 38-49, 52-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,11,19,20,37,50 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on September 27, 2007 has been entered. No claim amendments or arguments were filed with the request. Accordingly, as discussed in the previous Office action, claims 1, 11, 19, 20, 37, 50 and 51, to the extent that these claims are drawn to an isolated polypeptide or a composition comprising this isolated polypeptide are examined on the merits herewith.

Election/Restrictions

This application contains claims 24-36, 38-49, 52-65 drawn to an invention nonelected with traverse in the reply filed on 05 Dec 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

Claims 1, 11, 19, 20, 37, 50 and 51 recite a polypeptide that is bound to a divalent metal ion. The preambles, however, still recite an isolated polypeptide. Because the claimed invention is drawn to a composition having two components, a polypeptide and a divalent metal ion, the claims should be amended to recite this composition.

Claims 37, 50 and 51 still contain portions that are drawn to numerous non-elected inventions. The claims should be amended to delete the non-elected subject matter. Additionally, the portion of claim 37 that is drawn to the elected invention does not appear to further limit claim 1 and appears to be a duplicate of claim 1. This portion of claim 37 should be deleted or amended.

Claim 1 is drawn to a fragment of SEQ ID NO:6, amino 373-503 (or to a fragment of that fragment). Claims 11, 19 and 20 recite that the larger fragment or the smaller fragment has 95%, 98% or 99% sequence identity to SEQ ID NO:6. Applicants appear to mean that the fragments of claim 1 have 95%, 98% or 99% sequence identity to the corresponding regions of SEQ ID NO:6. Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 11, 19, 20, 37, 50 and 51 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the claims still recite fragments of SEQ ID NO: 6- a) polypeptides that are a fragment of SEQ ID NO: 6 that have adhesion activity, these fragments containing amino acids 373-503 of SEQ ID NO: 6, and b) fragments of the polypeptides in a) that have adhesion activity. The claims recite also c) polypeptides comprising an amino acid sequence that has 95% sequence identity to amino acids 373-503 of SEQ ID NO:

6 and having adhesion activity and d) polypeptides comprising a fragment of an amino acid sequence that has 95% sequence identity to amino acids 373-503 of SEQ ID NO: 6, the polypeptides of d) having adhesion activity. The claims are broader in that the claimed polypeptides need have only a 92 amino acid fragment of SEQ ID NO: 6- the fragment from Ser378 to Asp469, as long as the polypeptide binds to anything, as Applicants have not disclosed what the claimed polypeptides adhere to- and narrower in that this Ser378, Ser380 and Asp469 are bound to a divalent metal ion. But, the claims are also broader in that they also recite that a claimed polypeptide may be any fragment of SEQ ID NO: 6 that binds to anything as long as this fragment is bound to a divalent metal ion by any three amino acid residues, because the claims recite that the divalent metal ion is bound to three "equivalent residues." An "equivalent residue" may be anything, as it is not defined in the specification. The specification provides only examples of equivalent residues, e.g., Thr instead of Ser and Glu instead of Asp.

Apart from SEQ ID NO: 6, no such polypeptides in categories a) – d) above are disclosed in the specification. Thus, one of skill in the art would have no idea which fragments Applicants have in mind that they wish to include within the scope of the claimed invention. Also, one of skill in the art would have no idea which fragments of SEQ ID NO: 6 have adhesion activity. Applicants note in their previous response that the region of amino acids 373-503 is the "adhesion molecule region," but this information was obtained by data mining, which provided probabilities but not actual data. Applicants have not reduced the claimed invention to practice, and they have not disclosed which amino acid residues in the region of positions 373-503 are critical for adhesion or what molecule or molecules SEQ ID NO: 6 adheres to. Additionally, Applicants have not disclosed that a region of SEQ ID NO: 6 folds into a three-dimensional conformation so that residues Ser378, Ser380 and Asp469 bind to a divalent metal ion. It is not

trivial to determine exactly which amino acids a metal ion binds to, particularly when non-ionic groups, such as hydroxyl groups, are involved.

Consequently, there is no evidence that any representative species of such large and varied genera- polypeptides in categories a) – d) above- were in the possession of the inventors at the time of filing. To satisfy the written description aspect of 35 U.S.C. 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed. Because no fragments with adhesion activity are disclosed (only SEQ ID NO: 6 is disclosed), the claims fail to satisfy the written description requirement.

In their previous response, Applicants assert that a representative number of species are disclosed because adhesion activity assays are well known in the art, as are procedures for making polypeptides that have 95% sequence identity to a given polypeptide while conserving certain residues. Applicants also cite a portion of the specification that discloses data mining tools to determine whether or not a polypeptide has adhesion molecule activity. Additionally, Applicants assert that the claims are adequately described because of Example 14 of the Written Description Guidelines.

In reply, to meet the written description requirement, specific guidance is required, not general teachings. Applicants have not disclosed an assay for adhesion activity that demonstrates that SEQ ID NO: 6 has adhesion activity. Thus, Applicants have not demonstrated that any fragments of SEQ ID NO: 6 have adhesion activity. The portion of the

specification cited by Applicants discloses a data mining procedure for predicting the probable structural homology of a polypeptide sequence. As noted above, Applicants' computer programs do not demonstrate that SEQ ID NO: 6 or any of its fragments have adhesion activity. As for Example 14, Applicants' situation is not analogous, because, in this Example, the claimed invention had been reduced to practice. The specification disclosed hard data including an actual "wet" assay for the activity of the claimed protein, and the claimed protein had been tested in a laboratory and found to have the claimed activity (see Revised Interim Written Description Guidelines, Example 14, pp. 53-55, http://www.uspto.gov/web/offices/pac/writtendesc.pdf.

In view of the foregoing, the claims still fail to satisfy the written description requirement.

Claims 1, 11, 19, 20, 37, 50 and 51 are again rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide having the amino acid sequence of SEQ ID NO: 6, does not reasonably provide enablement for a polypeptide in one of the following claimed categories:

a) polypeptides that are a fragment of SEQ ID NO: 6 that have adhesion activity, these fragments containing amino acids 373-503 of SEQ ID NO: 6;

b) fragments of the polypeptides in a) that have adhesion activity;

c) polypeptides comprising an amino acid sequence that has 95% sequence identity to amino acids 373-503 of SEQ ID NO: 6 and having adhesion activity; and

d) polypeptides comprising a fragment of an amino acid sequence that has 95% sequence identity to amino acids 373-503 of SEQ ID NO: 6, the polypeptides of d) having adhesion activity. The polypeptides of a) – d) have either a 92 amino acid fragment of SEQ ID NO: 6, the fragment from Ser378 to Asp469, or any three "equivalent residues" that bind a divalent metal

ion. As discussed above, "equivalent residues" are not defined in the specification and, therefore, may be any three amino acids (even non-naturally occurring ones) that form a three-dimensional shape bound around a divalent metal cation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. A detailed explanation of the Wands factors was provided in a previous Office action.

The amended claims do not address the enablement issue and are not enabled for the reasons below.

1.Breadth of the claims.

The claims are very broad because they recite any fragment of SEQ ID NO: 6 with adhesion activity that has three amino acid that are equivalent to Ser378, Ser380 and Asp469 in that they bind a divalent metal ion.

2. The nature of the invention.

The invention is designed to provide a novel polypeptide that has adhesion activity.

3. The state of prior art.

A detailed discussion of the prior art was provided in the previous Office action and is equally relevant here.

4. The relative skill in the art.

The relative skill in the art as it relates to the method of the invention is characterized by that of a M.D. or Ph. D. level individual.

5. The level of predictability in the art.

Because it is not known which fragments of SEQ ID NO: 6 have adhesion activity, or which amino acids in the region of positions 373-503 are necessary for adhesion activity, because it is not known that SEQ ID NO: 6 has actual adhesion activity and because it has not

been demonstrated that Ser378, Ser380 and Asp469 and their functional equivalents bind a divalent metal ion, thereby folding the polypeptide or polypeptide fragment into an active shape, the specification needs to have more detail as how to make and use the invention. Because the prior art and the instant specification do not disclose any fragments of SEQ ID NO: 6 having adhesion activity or fragments of SEQ ID NO: 6 containing equivalent residues that have divalent metal binding activity, it cannot be predicted that any fragments of SEQ ID NO: 6 would retain these activities. Further, because the divalent metal ion binding activity has not been demonstrated, it also not been demonstrated that folding SEQ ID NO: 6 around a divalent metal ion imparts a three-dimensional active form that endows this complex with pharmaceutical and vaccine properties, i.e., protective-antibody-inducing properties.

6. The amount of guidance present.

Applicants have not provided any guidance for preparing fragments of SEQ ID NO: 6 that have adhesion activity or divalent metal ion binding activity.

7. The existence of working examples.

As mentioned previously, the specification contains a data-mining working example that describes how SEQ ID NO: 6 was identified. There are no working examples related to fragments of SEQ ID NO: 6 that have adhesion activity or divalent metal binding activity.

8. The quantity of experimentation necessary.

To prove that a polypeptide corresponding to one of claimed categories a) – d) above has adhesion activity or divalent metal binding activity, many experiments would have to be conducted under a wide range of conditions. In these experiments, many different polypeptides that are many different fragments of SEQ ID NO: 6 would have to be prepared. Each fragment would have to have a different number of amino acids deleted, and for each number of amino acids deleted, the deletions would have to be in many different positions. Each of these many

polypeptides would have to be tested for adhesion activity and for divalent metal binding activity. Each of these many polypeptides, including SEQ ID NO: 6, would have to be tested for pharmaceutical activity and vaccine activity, once bound to a divalent metal ion and folded into the active form.

Applicants have not provided any assays; consequently, an adhesion assay and a divalent metal ion binding assay would have to be developed. A target molecule would have to be identified to which these polypeptides adhere, although, firstly, it would have to be determined to which molecules SEQ ID NO: 6 adheres, as Applicants have not provided this information. Adhesion and divalent metal ion binding would have to be tested for each polypeptide under a wide range of conditions, e.g., buffers, temperatures, concentrations of the adhesion polypeptide and the target ligand, or concentrations of the adhesion polypeptide and the divalent metal ion. Additionally, diseases would have to be identified that are treated with the folded polypeptide-divalent metal ion complex, and assays for pharmaceutical activity would have to be developed and carried out. It would also have to be shown that these complexes can elicit the production of protective antibodies to these diseases, and assays for antibody production and disease protection would have to be developed and carried out.

These types of experiments and data are missing from the specification. A great deal of guidance is needed to establish that a fragment of SEQ ID NO: 6 has adhesion activity and divalent metal ion binding activity because these polypeptides are claimed and no disclosure of such polypeptides is provided. Even if one such fragment could be made or identified, by random, trial-and-error deletion or by identification in an assay, without a very large amount of data, such a result could not be expected with a different fragment under different assay conditions or in a different assay.

Therefore, the claims again fail to satisfy the enablement requirement.

Applicants assert that the claims meet the enablement requirement because a region with adhesion activity has been identified. Applicants also assert that it would not be undue experimentation to determine the scope of the invention because evidence that the claimed polypeptides have adhesion activity can be assessed by structural means. Applicants further assert that, to have adhesion activity, all of the claimed polypeptides will display equivalent folds to ADS5 because they possess Ser378, Ser380 and Asp 469 or equivalent residues that form a divalent metal ion binding site. Applicants note that the combination of these amino acid residues and amino acid residues 373-503 confers adhesion molecule annotation.

In reply, as discussed above, because of the fragment language in the claims, the claims encompass much more than the polypeptides addressed in Applicants' remarks, i.e., much more than polypeptides comprising amino acids 373-503 of SEQ ID NO: 6. As also discussed above, Applicants have not shown that their claimed fragments of SEQ ID NO: 6 have adhesion activity or divalent metal ion binding activity. Applicants' remarks are confusing because the region of amino acids 373-503 includes the amino acids that Applicants' allege have divalent metal ion binding activity, i.e., amino acids 378, 380 and 496. Thus, it is not clear whether Applicants are asserting that adhesion activity and divalent metal ion binding activity are two different activities or the same activity. It is not clear if Applicants' meaning is that what the polypeptide of SEQ ID NO: 6 adheres to is a divalent metal ion. If this region of amino acids 373-503 adopts a fold so that it binds a divalent metal ion, can it or does it also bind to something else?

As for identifying a region with adhesion activity, Applicants have identified a putative region that has not been tested, either as a fragment or in the whole polypeptide. As for "undue experimentation to determine the scope of the invention," the rejection is that it would be undue experimentation to figure out how to practice the scope of the claimed invention. Determining

the scope of the invention is a matter of claim interpretation, not enablement. As for assessing adhesion activity by structural means, Applicants' structural means is data mining software, and, as discussed above, what is required are sufficient hard data obtained from experiments on a number of fragments of SEQ ID NO: 6, i.e., "wet" experiments. Applicants' data mining provides statistical probabilities for SEQ ID NO: 6, but not for its fragments. As for conferring adhesion molecule "annotation," likewise, it is hard evidence of adhesion molecule activity that is required but lacking, not statistical probabilities.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 11, 19, 20, 37, 50 and 51 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection has been discussed in the previous Office actions.

Claim 1 recites the term "equivalent residues." As discussed previously, this term is not defined in the specification, although two examples are provided. Applicants assert that this term is defined, but, to reiterate, this is not a definition. The specification does not contain a statement that by "equivalent residues" Applicants mean x or y or a discrete and concrete group of amino acids. Appropriate correction is still required. Applicants may delete this term from the claims.

Claim Rejections - 35 USC § 101 and 35 USC § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 11, 19, 20, 37, 50 and 51 are again rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. This rejection has been discussed in a previous Office actions.

Applicants assert that the claimed invention has utility because ADS5 is an adhesion molecule with a metal-binding domain, and the metal-binding domain is critical for the activity of the molecule. Applicants assert that adhesion molecules play a role in diseases, particularly inflammatory diseases, and, therefore, ADS5 is useful for diagnosing and treating inflammatory diseases. Applicants also assert that ADS5 has an I domain, which is the site of interaction between integrins and intracellular adhesion molecules, and Applicants cite Huth et al. Applicants further assert that ADS5 is associated with Sjogren's syndrome, an autoimmune disease.

In reply, as discussed at length above, the claims are drawn to a great number of polypeptide fragments, as well as to SEQ ID NO: 6, for which no specific and substantial utility or well-established utility has been provided. Applicants' comments are limited to SEQ ID NO: 6. Applicants have not asserted that the claimed fragments have the required utility. As for SEQ ID NO: 6, the specification contains no disclosure that this polypeptide is associated with any specific disease or that this polypeptide may be used to treat or diagnose any disease. Applicants note that SEQ ID NO: 6 is associated with Sjogren's syndrome, but Applicants have not explained how this polypeptide is associated or how it used to treat this disease. This association may provide a utility for SEQ ID NO: 6, but not for any other claimed polypeptide. As for Huth et al., this reference discloses the I domain of CD11a in T-cells. Applicants have not indicated to what extent this I domain is related to SEQ ID NO: 6. Thus, the specification

does not disclose that SEQ ID NO: 6 has an I domain. As for the metal-binding domain, as discussed above, Applicants have not shown that SEQ ID NO: 6 actually binds to metal ions.

In view of the foregoing, the rejection of record is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 11, 19, 20 and 37 remain rejected under 35 U.S.C. 102(b) as being anticipated by Deutscher et al. ("Molecular analysis of the 60-kDa human Ro ribonucleoprotein, Proc Natl Acad Sci USA 85:9479-9483, 1988, see also the enclosed sequence alignment from searching the PIR database, Result 1). This rejection has been discussed in previous Office actions. As previously discussed, Deutscher et al. disclose the polypeptide of SEQ ID NO: 6 (100% sequence identity). This polypeptide was produced recombinantly in HeLa cells. Because the polypeptide of Deutscher et al. is the same as that of SEQ ID NO: 6, it also binds divalent metal cations via the same amino acids. When the polypeptide is present in a host cell, the polypeptide is bound to divalent metal ions, because the cytoplasm of host cells contains various divalent metal cations, such as calcium, zinc and magnesium. The host cell is a composition comprising the polypeptide of SEQ ID NO: 6 bound to a divalent metal ion. Therefore, the rejection of record is maintained.

Applicants assert that the claimed invention is not anticipated because their polypeptide does not form part of a ribonucleoprotein complex, does not associate with RNA and does not associate with a zing finger for DNA binding or RNA-protein recognition. In reply, Applicants' polypeptide is the same as that of Deutscher et al. The two sequences are identical. As a result, it necessarily has all of the properties of the polypeptide of Deutscher et al. Applicants have not tested their polypeptide and shown that it does not have these properties. Thus, Applicants' arguments are not persuasive.

Claims 1, 11, 19, 20 and 37 remain rejected under 35 U.S.C. 102(e) as being anticipated by Venter et al. (US 6,812,339, see also the enclosed sequence alignment from searching the issued patents database, Result 1). This rejection has been discussed in the previous Office actions. As previously discussed, Venter et al. disclose the polypeptide of SEQ ID NO: 6 (100% sequence identity) and that this polypeptide may be produced recombinantly in any conventional host cell. Because the polypeptide of Venter et al. is the same as that of SEQ ID NO: 6, it also binds divalent metal cations via the same amino acids. When the polypeptide is present in a host cell, the polypeptide is bound to divalent metal ions, because the cytoplasm of host cells contains various divalent metal cations, such as calcium, zinc and magnesium. The host cell is a composition comprising the polypeptide of SEQ ID NO: 6 bound to a divalent metal ion. Therefore, the rejection of record is maintained.

Applicants assert that their invention is not anticipated because Venter et al. is related to SNP's in a large number of genes, and Venter et al. do not disclose adhesion activity and divalent metal ion binding activity. In reply, similarly to the above rejection, Applicants' polypeptide is the same as that of Venter et al. The two sequences are identical, as the comprising language of the claims does not exclude the presence of additional amino acids at

the N-terminus of SEQ ID NO: 6. As a result, the polypeptide of Venter et al. necessarily has all of the properties of SEQ ID NO: 6. That Venter et al. is related to SNP's does not in any way detract from the relevant portions of this disclosure. Thus, Applicants' arguments are not persuasive.

Claims 1, 11, 19, 20 and 37 remain rejected under 35 U.S.C. 102(e) as being anticipated by Burckhardt et al. (US 2003/0109001, see also the enclosed sequence alignment from searching the Geneseq database, Result 3). This rejection has been discussed in the previous Office actions. As previously discussed, Burckhardt et al. disclose the polypeptide of SEQ ID NO: 6 (SEQ ID NO: 6 has 100% sequence identity to amino acids 13-550 of Burckhardt et al.'s SEQ ID NO: 1) and that this polypeptide may be produced recombinantly in a prokaryotic host cell. Because the polypeptide of Burckhardt et al. is the same as that of SEQ ID NO: 6, it also binds divalent metal cations via the same amino acids. When the polypeptide is present in a host cell, the polypeptide is bound to divalent metal ions, because the cytoplasm of host cells contains various divalent metal cations, such as calcium, zinc and magnesium. The host cell is a composition comprising the polypeptide of SEQ ID NO: 6 bound to a divalent metal ion. Therefore, the rejection of record is maintained.

Applicants assert that their invention is not anticipated because the polypeptide of Burckhardt et al. is a splice variant of theirs and does not have adhesion activity because it is part of a ribonucleoprotein complex. In reply, similarly to the above rejections, Applicants' polypeptide is the same as that of Burckhardt et al. The two sequences are identical, as the comprising language of the claims does not exclude the presence of additional amino acids at the N-terminus of SEQ ID NO: 6. As a result, the two polypeptides necessarily have all the same functional properties. That Burckhardt et al. disclose a ribonucleoprotein does not in any

way detract from the relevant portions of this disclosure. Thus, Applicants' arguments are not persuasive.

Claims 1, 11, 19, 20 and 37 remain rejected under 35 U.S.C. 102(b) as being anticipated by Keene (US 5,541,291, see also the enclosed sequence alignment from searching the Geneseq database, Result 8). This rejection has been discussed in the previous Office actions. As previously discussed, Keene et al. disclose a polypeptide that has 64% sequence identity to SEQ ID NO: 6 and 100% sequence identity to amino acids 194-538 of SEQ ID NO: 6. Thus, Keene discloses a fragment of SEQ ID NO: 6 that contains the adhesion region of ADS5 (amino acids 373-503) and amino acids Ser378, Ser380 and Asp469 of SEQ ID NO: 6. Keene et al. disclose that this polypeptide may be produced recombinantly in a prokaryotic host cell (see col. 7, lines 21-61). Because the polypeptide of Keene et al. contains amino acids 373-503 of SEQ ID NO: 6, it also has adhesion activity and binds divalent metal cations via the same amino acids. When the polypeptide is present in a host cell, the polypeptide is bound to divalent metal ions, because the cytoplasm of host cells contains various divalent metal cations, such as calcium, zinc and magnesium. The host cell is a composition comprising a polypeptide comprising amino acids 373-503 of SEQ ID NO: 6 bound to a divalent metal ion. Therefore, the rejection of record is maintained.

Applicants assert that their invention is not anticipated because the polypeptide of Keene et al. is a ribonucleoprotein and does not have adhesion activity or divalent metal ion biding activity. In reply, similarly to the above rejections, Applicants' polypeptide is the same as that of Keene et al. within the region of amino acids 373-503, the region that Applicants assert has these two activities. The two sequences are identical in this region, and the claims include a fragment of SEQ ID NO: 6 having this region. As a result, the polypeptide of Keene et al.

necessarily has all of the properties of Applicants polypeptide. That Keene et al. disclose a ribonucleoprotein does not in any way detract from the relevant portions of this disclosure. Thus, Applicants' arguments are not persuasive.

No claim is allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652

rk/2007-10-31

JON WEBER
SUPERVISORY PATENT EXAMINER